

### **REMARKS**

Applicant respectfully requests further examination and reconsideration in view of the amended claims and the arguments set forth fully below. In the Final Office Action mailed November 29, 2006, claims 1, 3, 5, 7, 9, 10, 12-15, 17, 18 and 20 have been rejected. In response, the Applicant has submitted the following remarks amended claims 1, 3, 5, 7, 9, 12, 18 and 20, and cancelled claims 2, 4, 6, 8, 11 and 16. Accordingly, claims 1, 3, 5, 7, 9-10, 12-15 and 17-20 are pending. Favorable reconsideration is respectfully requested in view of the amended claims and the remarks below.

#### **Rejections Under 35 U.S.C. §102**

Claim 17 has been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Application Publication No. 2004/0230456 to Lozier et al (hereinafter Lozier). The Applicant respectfully disagrees with this rejection.

Within the Office Action it is stated that as currently written, claim 17 requires that the single report include at least one of “electrocardiogram data, electrocardiogram pattern, an electrogram correlation and an electrogram measurement, image data, an image pattern, an image correlation, an image measurement, a mathematical measurement, a parameter value and a range,” and as discussed in the last Office Action, because Lozier disclosures including a single report of an electrogram measurement 203, that Lozier anticipates the current claim 17. By the above amendment, the Applicants have amended claim 17 such that the Lozier reference does not anticipate the claim 17 now as written.

As stated previously, in contrast to the teachings of Lozier, the system and method of the present invention includes a set of data acquisition devices capable of collecting patient data including ECG and image data, and a set of analysis modules configured to determine a mathematical measurement, an ECG measurement and an image measurement, wherein a decision support module receives these measurements and determines a level of heart disease in the patient. A diagnosis module then calculates an

SCD score based on the level of heart disease. Furthermore, the method and system of the present invention includes a single report based on data acquired from the data acquisition devices, such that the single report includes patient identifiers, patient history, physician identifiers, ECG data, ECG patterns, ECG correlation, ECG measurement, image data, image patterns, image correlations, image measurements, mathematical measurements, parameter values, ranges, SCD risk score, diagnosis, recommended treatments, and recommended follow up tests.

Claim 17 is directed to a method of displaying a prediction of sudden cardiac death, the method comprising generating a single report based on data acquired from a plurality of medical devices, the single report including a patient history and a physician identifier, the single report including a set of electrocardiogram data, an electrocardiogram pattern, an electrocardiogram correlation, an electrocardiogram measurement, image data, an image pattern, an image correlation, an image measurement, a mathematical measurement, a parameter value, and a range, and the single report including at least one of a sudden cardiac death risk score, a diagnosis, a recommended treatment, and a recommended follow-up test, and displaying the single report for review by medical personnel.. As discussed above, Lozier does not teach a single report including image data, image patterns, image correlations, image measurements, mathematical measurements, parameter values, ranges, recommended treatments, nor a recommended follow up test. For at least these reasons, the independent claim 17 is allowable over the teachings of Lozier.

*Rejections Under 35 U.S.C. §103*

Claims 1, 5, 7, 9, 10 and 12-15 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Publication No. 2002/0188214 to Misczynski (hereinafter Misczynski) in view of Lozier. The Applicant respectfully disagrees with this rejection.

Misczynski teaches a system and process for analyzing a medical condition of a user including a portable information receiving device, an information processing device and a remote storage and processing device (Misczynski, abstract). Within the Office Action, the Examiner simply cites Figure 1a of Misczynski, without providing any further analysis of this piece of prior art. However, referring to the description of Misczynski, paragraph 57, the Applicants respectfully submit that the Miczynski reference provides very little description of Figure 1a at all. The pertinent description of Figure 1a is included in paragraph 57 and states that, “....this information..., is then communicated to information processing device 200. Once this information has been received it is entered into a FIFO buffer 214 then a C buffer 216 before it is analyzed. Information processing device 200 analyzes this information and then determines whether the user is experiencing any abnormal systems. Next, information processing device 200 either sends an alarm or controls signal to the user, portable information device 100, or to a medical professional if the user is experiencing any abnormal symptoms. Information processing device 200 can also signal to portable information device 100 to cause various actions to the user, or the user’s environment.” Referring to this passage and to Figure 1a, the Applicants respectfully submits that Misczynski processes signals collected from a patient, but does not include specific teachings of comparing this patient data to stored patterns to determine a measurement with an analysis module, nor comparing the measurement to arrange to determine a correlation, wherein the correlation reflects a level of heart disease. These limitations are clearly described and claimed in claims 1 and 12 of the present invention.

Lozier teaches a software system for identifying patients that may be appropriate candidates for implantation with an implantable cardioverter/defibrillator. Lozier does not teach an ACE system configured to compare a set of patient data to stored patterns to determine a measurement with an analysis module, nor further configured to compare the measurement to determine a correlation with a decision support module, wherein the correlation reflects a level of heart disease, and further a diagnosis module configured to

diagnose a sudden cardiac death risk score based on the level of heart disease. Furthermore, Lozier does not teach a method of displaying a prediction of sudden cardiac death comprising generating a single report based on data acquired from a plurality of medical devices, wherein the single report includes image data, image pattern, image correlation, image measurement, mathematical measurement, parameter value, and a range. Lozier also does not teach a single report including a recommended treatment and a recommended follow up test.

Claim 1 is directed to a method of predicting sudden cardiac death in a patient, the method comprises acquiring patient data from a plurality of medical equipment databases with a set of acquisition devices, comparing the patient data to stored patterns to determine a measurement with an analysis module, comparing the measurement to a range to determine a correlation with a decision support module, wherein the correlation reflects a level of heart disease, and diagnosing a sudden cardiac death risk score with a diagnosis module. As described above, neither Lozier, Miczynski, nor their combination teach comparing patient data to determine a measurement and further comparing the measurement to a range to determine a correlation. For at least these reasons, the independent claim 1 is allowable over the teachings of Lozier, Miczynski and their combination.

Claims 5, 7, 9 and 10 are dependent upon the independent claim 1. As discussed above, the independent claim 1 is allowable over the teachings of Lozier, Miczynski and their combination. Accordingly, claims 5, 7, 9 and 10 are also allowable as being dependent upon an allowable base claim.

Claim 12 is directed to a computer program embodied by a computer readable medium capable of being executed by a computer, the computer program for use in a sudden cardiac death predication system comprising an acquisition module that communicates over a network to acquire patient data from a plurality of medical equipment databases, an analysis module that analyzes the patient data and calculates a plurality of measurements, a decision support module that analyzes the plurality of

measurements and determines a level of heart disease, a diagnosis module that provides a medical diagnosis and sudden cardiac death prediction score based on the level of heart disease, and a report module that provides a single report including at least the sudden cardiac death prediction score. As discussed above, neither Lozier, Miczynski, nor their combination teach the analysis module, the decision support module, nor the diagnosis module as taught and claimed in the present invention. For at least these reasons, the independent claim 12 is allowable over the teachings of Lozier, Miczynski, nor their combination.

Claims 13-15 are dependent upon the independent claim 12. As discussed above, the independent claim 12 is allowable over the teachings of Lozier, Miczynski, nor their combination. Accordingly, claims 13-15 are also allowable as being dependent upon an allowable base claim.

Claims 3 and 18 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Miczynski in view of Lozier as applied to claims 1, 5, 7, 9, 10, and 12-15 above and further in view of U.S. Patent No. 6,370,423 to Guerrero et al. (hereinafter Guerrero). The Applicants respectfully disagree with this rejection.

Claim 3 depends upon the independent claim 1. As discussed above, the independent claim is allowable over the teachings of Lozier. For at least these reasons, claim 3 is allowable as being dependent upon an allowable base claim. Claim 4 has been cancelled.

Guerrero teaches a method of analyzing biological signals representative of voltages changes, including obtaining an analog biological signal representative of voltage changes, using digital processing software to digitize the biological signal, displaying the process biological signal in analog form on the display in a time compressed format, wherein an amount of compression for the time compressed format is selected such that graphical patterns are made perceivable on the display that signify an abnormality in the biological signal, and visually analyzing the biological signal under the display to characterize the abnormality (Guerrero, abstract). However, Guerrero does not

teach a decision support module nor a diagnosis module configured to generate a single report based on data acquired from a plurality of medical devices, wherein the single report includes image data, image pattern, image correlation, image measurement, mathematical measurement, parameter value, and a range. Guerrero also does not teach a single report including a recommended treatment and a recommended follow up test.

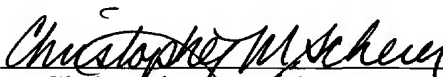
Claim 18 is directed to a system for determining a risk or predicting sudden cardiac death and includes calculating a sudden cardiac death risk score based on patient data. For the same reason as indicated for claims 1 and 12, claim 18 is also allowable over Miczynski, Lozier, and Guerrero.

Claim 20 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Miczynski in view of Guerrero. Claim 20 is directed to a medical device for determining a risk or predicting sudden cardiac death, and includes calculating a sudden cardiac death risk score based on patient data. For the same reasons as indicated in the argument for claims 1 and 12, claim 20 is allowable over Miczynski and Guerrero.

For these reasons, Applicant respectfully submits that all of the claims are now in a condition for allowance, and allowance at an early date would be appreciated. Should the Examiner have any questions or comments, they are encouraged to call the undersigned at 414-271-7590 to discuss the same so that any outstanding issues can be expeditiously resolved.

Respectfully submitted,

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